REMARKS

Claims 1-21, 31-48 and 53 are pending. Claims 1-21, 31-48, and 53 stand rejected. In this submission for RCE, Applicant has presently amended claims 1, 31 and 53. In view of these amendments, and as discussed below, it is submitted that the application is now in condition for allowance.

Summary of the Invention of the Present Application:

The invention of the present application provides a composition including the tannate salts of phenylephrine and pyrilamine as active pharmaceutical ingredients. The method of obtaining the composition involves a conversion process, which comprises the steps of mixing a dispersing agent and tannic acid in a suitable solvent to generate a mixture in liquid form, referred to as a dispersion. A solution of phenylephrine and pyrilamine as salts or in the free base form dissolved in a solvent, is added slowly to the dispersion to generate the tannate salt. The resulting tannate salts of phenylephrine and pyrilamine are then subsequently processed into suitable dosage forms, such as a suspension or tablets. The use of the dispersion prevents the clumping and aggregation of the tannate salt formed. As a result, the problem described in the application of prior art pharmaceutical compositions that contain variable, and sometimes sub-therapeutic, levels of active pharmaceutical ingredients is ameliorated by providing a composition including a generally uniform amount of active

pharmaceutical ingredients included in the dosage forms. Since the tannate salts of phenylephrine and/or pyrilamine are generated and incorporated in-situ into the dosage form during the manufacturing process, the purification and drying steps, which are generally required for the isolation of the tannate salts, are also eliminated.

To provide the composition in a suspension, the dispersion of the tannate salts in the solvent obtained from the conversion process is transferred to a suitable liquid medium, which includes co-solvents, preservatives, sweetening/flavoring, pH adjusting agents, coloring agents, thickening agents and anti-caking agents. The resulting mixture is then processed into suitable liquid dosage forms. Alternatively, the composition may be provided in tablet form. In this method, the tannate salts in the solvent obtained from the conversion process are mixed with a diluent and dry binding/matrix forming agents, and are wet granulated by spraying with a binder solution. The granulation is subsequently dried and then is dry blended with more diluent, sweetening agents, hardness increasing agents, coloring agents and flavoring agents as necessary. The resulting granulate can be processed into tablets.

Claim Rejections 35 U.S.C. § 103:

The Examiner has maintained the rejection of claims 1-21, 31-48 and 53 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,287,597 (Gordziel) in view of U.S. Patent No. 5,599,846 (Chopdekar). Applicant respectfully disagrees.

Applicant first notes that claims 1, 31, and 53 have been presently amended in the application. In particular, these claims have been amended to recite that the composition comprises a plurality of active pharmaceutical ingredients, wherein those ingredients are present as a plurality of dosage forms having "an amount of said active pharmaceutical ingredients, said amount being generally uniform in each of said dosage forms when compared one to another." As described above, and throughout the application, the novel process of using a separate dispersion allows for general uniformity of the amounts of active pharmaceutical ingredients within a batch of the present composition, as opposed to the variable levels of active pharmaceutical ingredients which were present in compositions of the prior art. Applicant submits that since this general uniformity is generated by the particular process of the claimed invention, the differing steps of the present process over that of the prior art provide for differences in the compositions that are formed by the respective processes. Applicant further asserts that since neither Gordziel nor Chopdekar disclose the process steps necessary to generate such general uniformity of active pharmaceutical ingredients, the compositions produced in Gordziel and Chopdekar do not exhibit such general uniformity.

In particular, referring to page 3, lines 1-11, the present application describes the "old" isopropanol and water routes of forming tannate salts. These "old" routes are the very ones disclosed in both Gordziel and Chopdekar. Next, at page 3,

lines 12-23, the present application describes that the tannate salts produced by either one of those old routes vary in their purity, and result in the amount of active pharmaceutical ingredient varying from batch to batch. At page 4, lines 11-15, the present application then describes that the present invention eliminates this problem of variability of active pharmaceutical ingredient by the novel process of the present invention. This process includes the creation of a separate dispersion (for example, a dispersing agent and tannic acid in purified water), to which an aqueous solution of active pharmaceutical ingredient (phenylephrine or pyrilamine) is added slowly to generate the tannate salt. This process prevents clumping and aggregation of the tannate salt and reduces the variability of the active drug content, thus creating a composition which has an increased certainty that the amount of active pharmaceutical ingredient is delivered in a therapeutic range. In further support for the present amendments and for Applicant's position, page 11, lines 18-20 of the present application note that the dispersing agent "prevents clumping and aggregation . . . and promotes uniformity. . . ." Also, at page 16, lines 8-9, the application states that blend samples taken during mixing "showed good uniformity of the actives."

Applicant notes that neither Gordziel nor Chopdekar discloses the process by which the general uniformity of active pharmaceutical ingredient in the present composition is achieved. In fact, as noted above, both Gordziel and Chopdekar describe the "old" routes of preparation, which Applicant describes in the application as

forming compositions which vary in the amount of active pharmaceutical ingredient from batch to batch. Thus, Applicant submits that the composition disclosed in Gordziel or Chopdekar will not exhibit such general uniformity, and rather disclose compositions which exhibit variable levels of active pharmaceutical ingredient from dosage form to dosage form of the composition. Applicant further notes that claims 1, 31, and 53 of the present application have been presently amended to recite a limitation to this general uniformity of amounts of active pharmaceutical ingredients. As a result, Applicant submits that it cannot be the case that the composition disclosed in Gordziel is the same as the composition claimed in the present application. Applicant further submits that a combination of Gordziel with Chopdekar also cannot render such a composition obvious, since Chopdekar also does not describe the process used to achieve the general uniformity of the amounts of active pharmaceutical ingredients, and thus does not disclose a composition exhibiting such general uniformity. Thus, Applicant asserts that any combination of Gordziel and Chopdekar fails to teach every element of the invention as presently claimed.

In view of the above, Applicant asserts that the combination of the Gordziel and Chopdekar references do not teach all the limitations of independent claims 1, 31, and 53 as presently amended. As such, Applicant respectfully requests a withdrawal of the rejection of claims 1-21, 31-48, and 53 under 35 U.S.C. §103.

Conclusion:

For the foregoing reasons, it is submitted that all claims are patentable and a Notice of Allowance is respectfully requested.

Enclosed is a check in the amount of $860.00, representing the fee for Request for Continued Examination ($385.00) and the fee for a three-month extension of time ($475.00). Applicants believe that no additional fees are due. If, however, any additional fee or surcharges are deemed due, please charge same or credit any overpayment to Deposit Account No. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,

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